OCT 1 9 2006

K062336

# SECTION 5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

## 5.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | |
|---|---|
| **APPLICANT** | OptiMedica Corporation |
| **TRADE NAME:** | OptiMedica Laser Indirect Ophthalmoscope (LIO) |
| **COMMON NAME:** | Laser Indirect Ophthalmoscope (LIO) |
| **DEVICE CLASSIFICATION** | GEX<br>21 CFR 878.4810<br>Laser instrument, surgical, powered |

### 5.1 SUBSTANTIALLY EQUIVALENT TO:

The Laser Indirect Ophthalmoscope (LIO) is substantially equivalent in intended use and the same or similar technological characteristics (including treatment and aiming wavelengths, spot size, working distance and indirect ophthalmoscope used) as the Zeiss LIO (K924588). The OptiMedica LIO is also substantially equivalent to the delivery devices included in 510(k)s K022181 (Novus VARIA and Delivery Devices ) and K052526 (Novus 3000 and Delivery Devices ) by Lumenis and K991258 (Novus Verdi Delivery Systems) by Coherent.

### 5.2 DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The OptiMedica Laser Indirect Ophthalmoscope (LIO) is intended for use in the diagnosis and treatment of ocular pathology. The LIO illuminates and magnifies the fundus image. When connected to the Pascal Retinal Photocoagulator, the laser aiming and treatment beams are precisely focused and delivered to the patient's eye through the LIO.

## 5.3 INDICATION FOR USE

The OptiMedica LIO is indicated for the delivery of laser energy in eyes with retinal pathology. The OptiMedica LIO is indicated for use in the following ophthalmic treatments and conditions:

- Diabetic retinopathy (panretinal photocoagulation)
- Macular degeneration
- Peripheral neovascularization
- Retinal breaks
- Retinal detachments
- Retinal tears
- Lattice degeneration
- Pneumatic retinopexy reattachment procedures
- Segmental peripheral photocoagulation
- Segmental photocoagulation
- Cloudy vitreous cavities
- Pediatric retinal repairs (under general anesthesia)
- Delivery of laser energy through small pupils or to eyes with focal lens opacities

## 5.4 CONTRAINDICATIONS

Laser surgery with the OptiMedica LIO is contraindicated when an appropriate procedure cannot be performed safely. This occurs when tissue targets cannot be visualized properly. Under such circumstances, an important tissue structure adjacent to a target tissue might be photocoagulated inadvertently. Corneal opacities, cataract formation, and vitreous hemorrhage can all interfere with the laser surgeon's view of appropriate target structures. Treatment should be delayed until the visualization has adequately improved.

## 5.5 TECHNICAL CHARACTERISTICS

**Indirect Ophthalmoscope**

The OptiMedica LIO uses a Heine OMEGA 500 binocular indirect ophthalmoscope. Each of the predicate devices, including the Zeiss Laser Indirect Ophthalmoscope (K924588), the Lumenis Novus 3000 Delivery Devices (K052526), Lumenis Novus VARIA Delivery Devices (K022181), and Coherent Novus Verdi Delivery Systems (K991258) use a Heine binocular indirect ophthalmoscope as well.

**Usable Wavelengths**

The OptiMedica LIO is designed to be used with the Pascal Photocoagulator. This system produces 532nm light for treatment, and 635 nm light for aiming, identical to the Lumenis Novus 3000 (K052526), Lumenis Novus VARIA (K022181), Coherent Novus Verdi (K991258), and the Zeiss Visulas system used with the Zeiss Laser Indirect Ophthalmoscope (K924588).

**Eye Filter Optical Density**
The OptiMedica LIO eye safety filter optical density at the treatment wavelength is the same as all of the predicate devices, OD>5. The OptiMedica LIO also uses a photopically neutral filter to allow the high transmission of the aiming beam and white balance the image, making visualization easier and more realistic.

**Aerial Spot Size**
The OptiMedica LIO spot size for delivery through indirect surgical lens is 960μm. This is almost identical to that of the Lumenis Novus 3000 (K052526), Lumenis Novus VARIA (K022181), Coherent Novus Verdi (K991258), which are 973μm. The Zeiss Laser Indirect Ophthalmoscope (K924588) uses a 1060 μm spot.

**Working Distance**
The OptiMedica LIO working distance of 275mm lies right in the middle of the range specified by the predicate devices. The Lumenis Novus 3000 (K052526), Lumenis Novus VARIA (K022181), Coherent Novus Verdi (K991258) systems specify a 270mm working distance. The Zeiss Laser Indirect Ophthalmoscope (K924588) uses a 280mm working distance.

**Fiber Length**
The OptiMedica LIO fiber length of 5 meters is equal to that of the Zeiss Laser Indirect Ophthalmoscope (K924588), and slightly longer than that of the Lumenis Novus 3000 (K052526), Lumenis Novus VARIA (K022181), Coherent Novus Verdi (K991258) systems which use 4.6 meter long fibers.

**Electrical Requirements**
The OptiMedica LIO and all of the predicate devices use the same sort of illumination source, and therefore have the same electrical requirements.

**Cooling Methods**
The OptiMedica LIO and all of the predicate devices use the same sort of illumination source, and therefore have the same cooling requirements and methods.

**Weight**
The OptiMedica LIO and all of the predicate devices use the same sort of binocular indirect ophthalmoscope, and therefore have roughly the same weight.

**Dimensions**
The OptiMedica LIO and all of the predicate devices use the same sort of binocular indirect ophthalmoscope, and therefore have roughly the same dimensions.

### 5.6 PERFORMANCE DATA

Performance testing has been conducted with the OptiMedica LIO to establish the optical similarity of the OptiMedica LIO with respect to a predicate device, the Zeiss LIO, as a means to assess the relative clinical performance of the devices. This was accomplished by characterizing the optical performance of both laser delivery systems at their treatment and aiming wavelengths. Optical transmissions, as well as the delivered spot size and intensity profiles were measured.

### 5.7 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The indications for use for the OptiMedica LIO are similar to the predicate LIOs cited in this application. The safety of the materials used for the manufacture of LIO has previously been demonstrated. Testing demonstrates that the OptiMedica LIO is functionally equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2006

OptiMedica Corporation
% ClinReg Consulting Services, Inc.
Judy F. Gordon, D.V.M.
733 Bolsana Drive
Laguna Beach, California 92651

Re: K062336
Trade/Device Name: OptiMedica Laser Indirect Ophthalmoscope
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 7, 2006
Received: August 10, 2006

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

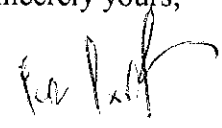
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K062336

Device Name: OptiMedica Laser Indirect Ophthalmoscope

Indications for Use:

The OptiMedica LIO is indicated for the delivery of laser energy in eyes with retinal pathology. The OptiMedica LIO is indicated for use in the following ophthalmic treatments and conditions:

- Diabetic retinopathy (panretinal photocoagulation)
- Macular degeneration
- Peripheral neovascularization
- Retinal breaks
- Retinal detachments
- Retinal tears
- Lattice degeneration
- Pneumatic retinopexy reattachment procedures
- Segmental peripheral photocoagulation
- Segmental photocoagulation
- Cloudy vitreous cavities
- Pediatric retinal repairs (under general anesthesia)
- Delivery of laser energy through small pupils or to eyes with focal lens opacities

The *CDRH Indications for Use Statement* for the OptiMedica LIO can be found on the following page.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

Page __ of __

**510(k) Number** K062336